

not to exceed the tolerances specified in table 2, calculated on the basis of the water capacity of the container on which the closure is to be used. Employ the analytical method described in § 175.300 of this chapter, adapting the procedural details to make the method applicable to closures; such as, for example, placing the closed glass container on its side to assure contact of the closure's food-contacting surface with the solvent.

TABLE 3—TYPES OF FOOD

- I. Nonacid (pH above 5.0), aqueous products; may contain salt or sugar or both, and including oil-in-water emulsions of low- or high-fat content.
- II. Acidic (pH 5.0 or below), aqueous products; may contain salt or sugar or both, and including oil-in-water emulsions of low- or high-fat content.
- III. Aqueous, acid or nonacid products containing free oil or fat; may contain salt, and including water-in-oil emulsions of low- or high-fat content.
- IV. Dairy products and modifications:
  - A. Water-in-oil emulsions, high- or low-fat.
  - B. Oil-in-water emulsions, high- or low-fat.
- V. Low-moisture fats and oils.
- VI. Beverages:
  - A. Containing alcohol.
  - B. Nonalcoholic.
- VII. Bakery products.
- VIII. Dry solids (no end-test required).

TABLE 4—TEST PROCEDURES WITH TIME-TEMPERATURE CONDITIONS FOR DETERMINING AMOUNT OF EXTRACTIVES FROM CLOSURE-SEALING GASKETS, USING SOLVENTS SIMULATING TYPES OF FOODS AND BEVERAGES

Conditions of use	Types of food (see table 3)	Extractant		
		Water <sup>2</sup>	Heptane <sup>1,2</sup>	8 percent alcohol <sup>2</sup>
A. High temperature heat-sterilized (e.g., over 212 °F).	I, IV-B .....	250 °F, 2 hr .....	.....	150 °F, 2 hr
B. Boiling water-sterilized .....	III, IV-A, VII .....	.....do .....	150 °F, 2 hr.	
	II .....	212 °F, 30 min .....	.....	
	III, VII .....	.....do .....	120 °F, 30 min.	
C. Hot filled or pasteurized above 150 °F.	II, IV-B .....	Fill boiling, cool to .....	.....	
	III, IV-A .....	100 °F.	120 °F, 15 min.	
	V .....	.....do .....	.....do.	
		.....	.....	
D. Hot filled or pasteurized below 150 °F	II, IV-B, VI-B .....	150 °F, 2 hr .....	.....	
	III, IV-A .....	.....do .....	100 °F, 30 min.	
	V .....	.....	.....do .....	120 °F, 24 hr.
	VI-A .....	.....	.....	
E. Temperature filled and stored (no thermal treatment in the container).	II, IV-B, VI-B .....	120 °F, 24 hr .....	70 °F, 30 min.	
	III, IV-A .....	.....do .....	.....do	
	V .....	.....	.....	70 °F, 48 hr.
	VI-A .....	.....	.....	
F. Refrigerated storage (no thermal treatment).	I, II, III, IV-A, IV-B, VI-B, VII.	70 °F, 48 hr .....	70 °F, 30 min .....	
	VI-A .....	.....	.....	
G. Frozen storage (no thermal treatment in the container).	I, II, III, IV-B, VII ...	70 °F, 24 hr .....	.	

<sup>1</sup> Heptane extractant not applicable to closure-sealing gaskets overcoated with wax.

<sup>2</sup> Time and temperature.

[42 FR 14572, Mar. 15, 1977; 42 FR 56728, Oct. 28, 1977, as amended at 47 FR 22090, May 21, 1982; 49 FR 5748, Feb. 15, 1984; 55 FR 34555, Aug. 23, 1990; 61 FR 14480, Apr. 2, 1996]

**§ 177.1240 1,4-Cyclohexylene dimethylene terephthalate and 1,4-cyclohexylene dimethylene isophthalate copolymer.**

Copolymer of 1,4-cyclohexylene dimethylene terephthalate and 1,4-cyclohexylene dimethylene isophthalate may be safely used as an article or component of articles used in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food, subject to the provisions of this section:

(a) The copolymer is a basic polyester produced by the catalytic condensation of dimethyl terephthalate and dimethyl isophthalate with 1,4-cyclohexanedimethanol, to which may have been added certain optional substances required in its production or added to impart desired physical and technical properties.

(b) The quantity of any optional substance employed in the production of the copolymer does not exceed the

amount reasonably required to accomplish the intended physical or technical effect or any limitation further provided.

(c) Any substance employed in the production of the copolymer that is the subject of a regulation in parts 174, 175, 176, 177, 178 and § 179.45 of this chapter conforms with any specification in such regulation.

(d) Substances employed in the production of the copolymer include:

(1) Substances generally recognized as safe in food.

(2) Substances subject to prior sanction or approval for use in the copolymer and used in accordance with such sanction or approval.

(3) Substances which by regulation in parts 174, 175, 176, 177, 178 and § 179.45 of this chapter may be safely used as components of resinous or polymeric coatings and film used as food-contact surfaces, subject to the provisions of such regulation.

(e) The copolymer conforms with the following specifications:

(1) The copolymer, when extracted with distilled water at reflux temperature for 2 hours, yields total extractives not to exceed 0.05 percent.

(2) The copolymer, when extracted with ethyl acetate at reflux temperature for 2 hours, yields total extractives not to exceed 0.7 percent.

(3) The copolymer, when extracted with *n*-hexane at reflux temperature for 2 hours, yields total extractives not to exceed 0.05 percent.

[42 FR 14572, Mar. 15, 1977; 49 FR 5748, Feb. 15, 1984, as amended at 55 FR 34555, Aug. 23, 1990]

#### **§ 177.1310 Ethylene-acrylic acid copolymers.**

The ethylene-acrylic acid copolymers identified in paragraph (a) of this section may be safely used as components of articles intended for use in contact with food subject to the provisions of this section.

(a) The ethylene-acrylic acid copolymers consist of basic copolymers produced by the copolymerization of ethylene and acrylic acid such that the finished basic copolymers contain no more than:

(1) 10 weight-percent of total polymer units derived from acrylic acid when

used in accordance with paragraph (b) of this section; and

(2) 25 weight-percent of total polymer units derived from acrylic acid when used in accordance with paragraph (c) of this section.

(b) The finished food-contact articles made with no more than 10 percent total polymer units derived from acrylic acid, when extracted with the solvent or solvents characterizing the type of food and under the conditions of its intended use as determined from tables 1 and 2 of § 176.170(c) of this chapter, yield net acidified chloroform-soluble extractives not to exceed 0.5 milligram per square inch of food-contact surface when tested by the methods prescribed in § 177.1330(e)(1), (3)(i) through (iv), (4), (5), and (6), except that

(1) The total residue method using 3 percent acetic acid, as prescribed in § 177.1330(e)(6)(i)(a), does not apply, and

(2) The net acidified chloroform-soluble extractives from paper and paperboard complying with § 176.170 of this chapter may be corrected for wax, petrolatum, and mineral oil as provided in § 176.170(d)(5)(iii)(b) of this chapter.

If the finished food-contact article is itself the subject of a regulation in parts 174, 175, 176, 177, 178, and § 179.45 of this chapter, it shall also comply with any specifications and limitations prescribed for it by that regulation.

(c) The finished food-contact layer made with basic copolymers containing more than 10 weight-percent but no more than 25 weight-percent of total polymer units derived from acrylic acid and with a maximum thickness of 0.0025 inch (2.5 mils) may be used in contact with food types I, II, IVB, VIA, VIB, VIIB, and VIII identified in table 1 of § 176.170(c) of the chapter under conditions of use B through H as described in table 2 of § 176.170(c) of this chapter, and in contact with food types III, IVA, V, VIIA, and IX identified in table 1 of § 176.170(c) of this chapter under conditions of use E through G as described in table 2 of § 176.170(c) of this chapter.

(d) The provisions of this section are not applicable to ethylene-acrylic acid